REMARKS

Upon entry of the accompanying amendment, claims 1, 3, 4, 6, 7, 9, 10, and 13-25 will be all the claims pending in the application.

In the accompanying amendment, claims 1, 3, 4, 6, 7, 9, 10, 13, and 14 have been amended to even more clearly state the claimed feature of the inventions and/or to correct typographical errors. For example, claim 1 has been amended to clearly be directed to a compound. Claims 3 and 4 have been amended to remove the term "derivative." Claims 13 and 14 have been amended in order to more clearly indicate that these claims are directed to a method. Claims 15-25 have been newly added and are dependent directly or indirectly from claim 1.

Support of the amendments may be found by, for example, original claims. No new matter has been added. Entry of the amendments and reconsideration of the application are respectfully requested.

Claim Rejections - 35 U.S.C. § 112

Claims 8-14 stand rejected under 35 U.S.C. 112, first paragraph.

1. Preventive activity

Applicants note that the Office asserts that the specification is enabling for a pharmaceutical composition as a therapeutic agent for asthma, but does not enable the prevention of any disease or the treatment of respiratory diseases.

Also, Applicants note that the Office acknowledges that the specification describes testing assays which are related to measuring the STAT 6-dependent reporter or Th2 differentiation activity, but asserts that the specification does not provide any disclosure regarding how the data of testing assays correlate to the preventive and therapeutic agents recited in the claims which may be used to a wide variety of therapeutic and/or preventive treatments.

Applicants respectfully disagree with the Office's interpretation of the term "prevention" as recited in the claims. The term "prevention" is used by the Applicants to mean prevention of onset of allergy symptoms such as asthma and such prevention is included in the notion of the 'treatment."

Nevertheless, solely in order to advance the prosecution of the instant application, Applicants have amended claims 9, 10, 13, and 14. Claims 8, 11 and 12 have been canceled.

B. COPD Treatment Activity

As to the activity of the treatment a chronic obstructive pulmonary disease (COPD) and of the inhibition of STAT6, Applicants respectfully submit that the specification sufficiently enable the claimed treatment of the COPD and inhibition of STAT6 for the following reasons.

With respect to this, claim 10 is amended to be directed to a method for treating COPO; claim 13 is amended to be directed to a method for inhibiting STAT6 activation, and claim 14 is amended to be directed a method for inhibiting Th2 cell differentiation induced by STAT6 activation. As mentioned above, claims 8, 11 and 12 have been canceled.

First, the specification of the present application states "it is expected that STAT 6 inhibitors are effective as agents for treating allergic or inflammatory respiratory diseases having

less influences upon infection protection, immunological function." Also, Example 264 in the specification of the present application shows the tests of STAT 6 inhibitors in the COPD-related animal model.

Applicants respectfully submit that it was known in the art that STAT 6 inhibitors are effective as agents for treating the COPD, as well as for treating allergy diseases.

There have been published several literatures which show the correlation between the STAT 6 inhibition and the COPD treatment.

For example, March *et al.*, "Effects of Concurrent Ozone Exposure On The Pathogenesis of Cigarette Smoke-Induced Emphysema in B6C3F_1 Mice," Inhalation Toxicology, 14, pp. 1187-1213 (2002) describes a model, which is similar to the system described in Example 264 of the present application, in which emphysema, the main pathologic condition of COPD, occurs by cigarette smoke and ozone.

Hautamaki, *et al.,* "Requirement for Macrophage Elastase for Cigarette Smoke-Induced Emphysema in Mice," Science, 277, pp. 2002-2004 (1997) explains that the COPD and emphysema induced by cigarette smoke.

Ofulue *et al.*, "Time course of neutrophil and macrophage elastinolytic activities in cigarette smoke-induced emphysema," The American Journal of Physiol. Lung Cell Mol Physiol, 275, pp. L1134-L1144 (1998) shows that invasion of neutrophilis into the lung occurs by cigarette smoke.

Also, the following literatures show that inhibition of STAT6 suppresses Th2 cell differentiation and signaling by IL13, resulting in effective treatment of allergy diseases.

Kuperman *et al.*, "Direct effects of interleukin-13 on epithelial cells cause airway hyperreactivity and mucus overproduction in asthma," Nature Medicine, 8:*, pp. 885-889 (Aug. 2002), discloses that mice in which IL-13 was overexpressed in the lung exhibited invasion of inflammatory cells, including neutrophils, into the lung (Fig. 3) and emphysema. However, mice in which IL-13 was overexpressed and further STAT6 was knocked-out, emphysema did not occur and invasion of neutrophils was inhibited (Fig. 3).

Zheng *et* al., "Inducible targeting of IL-13 to the adult lung causes matrix metalloproteinase-and cathepsin-dependent emphysema," J. of Clinical Investigation, 106, pp. 1081-1093 (Nov. 2000) reports that overexpression of IL-13 in the lung causes emphysema.

A copy of March et al., Hautamaki et al., Ofulue et al, Kuperman et al., and Zheng et al. is submitted in an Information Disclosure Statement accompanied with a necessary fee for the Office's consideration.

3. Conclusion

Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. § 112, first paragraph is not sustainable and request the rejection be withdrawn.

Claim rejection under 35 U.S.C. § 112, second paragraph

Claims 1-5 and 7-14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, claim 1 and 2 stand rejected on the ground that it is confusing if it is drawn to a compound or to a composition. Claim 1 has been amended in order to more clearly point out

the claimed invention and clearly states that it is drawn to a compound. Claim 2 has been canceled.

Claims 1, 3-5, 7, and 11-14 stand rejected on the ground that the term "derivative" is indefinite. While Applicants do not agree with the Office's assertion, the term "derivate" is deleted from claims 1, 3, 4, 7, 13 and 14. Claims 5, 11 and 12 have been canceled.

With regard to claims 8-10, the Office asserts that these claims merely recite an intended use for the composition of claim 7 and do not further limit claim 7. Claim 8 is canceled and claims 9 and 10 have been amended to more clearly set forth the claimed feature by amending them to be drawn to a method.

Claims 11-14 stand rejected on the ground that these claims are drawn to the use of a compound, while their independent claim 1 is drawn to a composition. Claim 1 has been amended to clearly show that it is drawn to a compound. Also, claims 13 and 14 have been amended to be drawn to a method, and claims 11-12 have been canceled.

Accordingly, it is believed that the rejections under 35 U.S.C. § 112, second paragraph are rendered by the amendments. Applicants respectfully request that the rejections be withdrawn.

Claim Rejections - 35 U.S.C. § 101

Claims 11 and 12 stand rejected under 35 U.S.C. 101. Claims 11 and 12 have been canceled.

Claim Rejections - 35 U.S.C. § 102

Claims 1-2 and 11-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by Taylor *et al.*, CAPLUS Abstract 55:33107 (1961) ("Taylor").

Claims 1, 2, and 11-14 stand rejected under 35 U.S.C. §102(b) as being anticipated by Hisamichi *et al.*, WO 99/31073 (U.S. Patent No. 6,432,963 is an equivalent and assigned to "Yamanouchi Pharmaceutical") ("Hisamichi").

Claims 1, 2, 11, and 12 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bradbury *et al.*, WO 00/39101 ("Bradbury").

Claim 1 has been amended. In the amended claim 1, the substituent B is cycloalkyl and Y is a single bond. Such amendments are supported by the specification, in particular Tables 12, 13, and 15-17.

None of Taylor, Hisamichi or Bradbury teaches a compound (I) wherein B is cycloalkyl.

Claims 11-12 have been canceled.

Claims 13 and 14 have been amended to be drawn to a method for inhibiting STAT6 and to a method for inhibiting Th2 cell differentiation. None of the above-referenced documents relied upon by the Office teaches or suggests the methods.

Therefore, it is believed that the amendments render the rejection under 35 U.S.C. § 102 moot.

Claim Rejections - 35 U.S.C. § 103

Claims 5 and 7-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hisamichi. The Office acknowledges that these claims differ from Hisamichi by reciting specific species or a more limited subgenus than Hisamichi.

Applicants understand that it is the Office's position that Hisamichi teaches the equivalency of compounds wherein the aryl group substituted by 1 to 4 substituents and, thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by Hisamichi, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents.

Without conceding the Office's assertion, claim 5 has been canceled solely for the purpose of advancing the prosecution.

Claims 7, 9 and 10 have been amended to refer to the compound of one of claims 1, 3 or 4. Hisamichi fails to teach or suggest the compound of claims 1, 3 or 4. There is no suggestion or teaching that motivates one skilled in the art to modify the teaching of Hisamichi to reach the claimed invention of claims 1, 3 or 4.

New claims 15-25 are dependent from claim 1 directly or indirectly and, thus, are patentable over Hisamichi.

Accordingly, Applicants respectfully request the rejection be withdrawn.

Duplicate Claims

It is stated in the Office Action that should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Also, it is stated that should claim 7 be found allowable, claims 8-10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

Without conceding the Office's assertion, claims 2 and 8 have been amended. Claims 9 and 10 have been rewritten to be drawn to a method claim.

Therefore, it is believed that the currently presented claims are in the condition of allowance.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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